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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,531	08/17/2001	Douglas W. Akers	B-124	4276

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EXAMINER	
PALABRICA, RICARDO J	
ART UNIT	**PAPER NUMBER**
3641	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/932,531	AKERS
	Examiner	Art Unit
	Rick Palabrica	3641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8,20-24,26-28 and 30-36* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8,20-24,26-28 and 30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action replaces and withdraws the 7/8/04 Office Action, including the Drawings objection therein, without prejudice to re-instating said objection in a future Office Action.

2. In view of newly found prior art and the need to address the new arguments presented by the Applicant in his 4/12/04 Appeal Brief, which the Examiner considers as an After Final Response, the 11/07/03 Final Office Action is withdrawn and replaced by this one.

The newly found art further shows that the claimed invention is obvious. The references cited in the After Final Response, which Applicant alleges to support his arguments, actually further proves the Examiner's conclusion that the term "activating a positron emitter" is repugnant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7, 20-24, and 26-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 7 recites the limitation of the data processing system operating the photon source to produce photons having the predetermined energies. As presently set forth, this configuration of an integrated source-data processing system is essentially a "black box" with no description of the internals thereof. The disclosure is insufficient in failing to set forth in an adequate and sufficient fashion, a description of this optimization program that would enable it to perform its intended function. If the applicant is of the opinion that there is a description in the prior art (in the form of literature, etc. having a date prior to the filing date of this application) of the internals of this black box, copies of said literature, etc. must be submitted for appropriate review by the Office. See *In re Ghiron et al.*, 169 USPQ 723, 727.

Claim 20 discloses the use of Doppler broadening algorithm, claims 21 and 22 disclose a positron lifetime algorithm, claim 23 discloses a selective activation algorithm and claim 24 discloses a three-dimensional algorithm. There is neither an adequate description nor enabling disclosure of what these algorithms are, and how and in what manner these algorithms should be selected and/or modified, as necessary, in order to achieve the intended results of the process.

In Paper No. 14, the Applicant states that several types of Doppler broadening techniques have been developed and the Doppler broadening algorithm may comprise the algorithm disclosed in U.S. Patent No. 6,178,218 B1. The Examiner reviewed this patent and found that, contrary to Applicant's allegation, "Doppler broadening algorithm" is **neither** referred to in the specification nor mentioned in the claims. As to the allegation that thee is a plurality of Doppler broadening techniques available, there is no support as to how one would select the appropriate technique for a specific application, and how said selected "technique" will be transformed to an "algorithm". Also, an algorithm (similar to an equation) will inherently include constants that have to be evaluated to "fit" particular conditions. There is no support as to how and in what manner said constants have to be evaluated.

A similar statement is made in Paper No. 14 and the specification regarding the plurality of available positron lifetime techniques/algorithms and three dimensional imaging techniques/algorithms. The same lack of enablement applies to these two cases.

As to the so-called "selective activation algorithm", this is another "black box" similar to the limitation of claim 7. The Applicant states in Paper No. 14 that a person having ordinary skill in the art could develop such algorithm based on his level of skill coupled with an understanding of the teachings of the present invention. This statement has no probative value because it is not supported by actual proof or evidence, i.e. it constitutes no more than uncorroborative statements of the Applicant.

Applicant cited the paper "Positron Annihilation Spectroscopy" as including descriptions of these algorithms as proof that they are known in the art. The Examiner notes that the reference only discusses positron lifetime determination (e.g., equations 17 and 18 on page 610) and Doppler broadening (e.g., equation 20 on page 620). There is no discussion in the reference of the three-dimensional algorithm.

Claims 26-28 are replete with the limitation, "activating a positron emitter by photon bombardment." The Examiner maintains that it is the stable precursor and not the positron emitter that is activated by photons. The activation of the stable precursor results in the production of an unstable positron emitter, which is already radioactive and transitions to a stable state by emitting positrons. Thus, the positron emitter does not need to be activated to emit positrons, contrary to the language of the claims. There is neither an adequate description nor enabling disclosure as to how and in what manner one activates a positron emitter that is already radioactive. Applicant's claim language implies that another positron emitter is formed by activation from an already existing positron emitter before positrons are produced. There is no support for the production of a new and different positron emitter from an already existing positron emitter. Note that in Table I of the specification, for example, only one positron emitter, i.e., ^{62}Cu, is shown for copper. Also, this positron emitter is not even shown as being "activated", contrary to the language of the claims. An activated element or isotope is normally designated with an asterisk (*), e.g. an activated ^{62}Cu would be shown as $(^{62}Cu)^*$. See also section 4 below.

4. Claims 7, 20-24, and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite and their metes and bounds cannot be determined for the reasons given in section 3 above.

The term "activating a positron emitter" is misdescriptive, as discussed in section 3 above. In his After Final Response (Appeal Brief), the Applicant alleges that the written description (paragraph 0044) defines "activate" as synonymous to "form", i.e., "activating a positron emitter" is the same as "forming a positron emitter." The Examiner disagrees that this definition is proper. While the applicant can act as his or her own lexicographer to specifically define a term, no term may be given a meaning repugnant to the usual meaning of the term. See MPEP 2173.05(a).

Applicant also alleges his "definition" is consistent with the ordinary meaning of the term as understood by others having ordinary skill in the art. He cites Miller (U.S. 4,980,901), Pongratz (U.S. 5,175,756) and Akers (U.S. 6,178,218) to support his case. The Examiner disagrees because these references actually confirm the Examiner's position. Both Miller and Pongratz use the term, "activated nuclei", (past tense of "activate"), which is totally different from applicant's term, "activating the positron emitter" (present tense of "activate"). The "activated nuclei" referred to by Miller and Pongratz, refers to nitrogen-13, an inherently unstable, positron emitter that does not need to the activated to emit positrons. This nitrogen-13 comes from a photonuclear

reaction of the stable precursor, nitrogen-14 (see column 3, lines 24+ in Miller and column 1, lines 23+ in Pongratz). Therefore, Applicant's position is not supported by either reference because Miller and Pongratz activate the nitrogen-14 (precursor) and not the nitrogen-13 (positron emitter).

Applicant cites Aker's claim language, "activating the positron emitter source" to support his allegation. Note that Akers refers to activating the source of the positron emitter and **NOT** the positron emitter itself. Akers specifically discloses "activating the positron emitter source by neutron activation" (see column 3, lines 9+). He further discloses that ^{58}Co (positron emitter) is formed by neutron capture from ^{59}Co (the positron emitter source or precursor). See column 4, lines 24+. Note that the neutron capture reaction is as follows: ^{59}Co (n, 2n) ^{58}Co. Akers does not activate the ^{58}Co. Again, Applicant's position is not supported by Akers.

Munro, III, et al. (U.S. 2002/0103410 A1) is another example of a prior art that refers to activating a stable precursor (positron emitter source) to produce an inherently radioactive positron emitter (see paragraph 0026). For example, Munro teaches activating stable xenon-124 to produce, xenon-125, a positron emitter. Munro does not activate the positron emitter.

Therefore, the above references clearly show that persons having ordinary skill in the art do not refer to activating the positron emitter, contrary to applicant's allegation. They also show that applicant's definition of "activating a positron emitter" is repugnant to the usual meaning of the term.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over: a) Akers et al. (U.S. 6,178,218 B1) in view of Richard B. Firestone, "The Berkeley Laboratory Isotopes Project, Exploring the Table of Isotopes," (http://ie.lbl.gov/education/isotopes.htm) alone; or b) Akers et al. in view of the combination of Firestone and Obermayer (U.S. 3,662,882). Akers et al. disclose the applicant's claims except for the use of a photon source.

Akers et al. disclose an apparatus and method for performing nondestructive examination of a metal specimen using neutron activated positron annihilation. The positron emitter source is formed within the metal specimen by neutron activation and the gamma rays from positron annihilation are detected by a Ge or Ge(Li) detector (see Abstract and Figs. 1 and 2). Applicant's claim language. "data processing system producing data indicative of the presence or absence of a lattice defect in the specimen being tested" reads on the Canberra Inspector multichannel analyzer system used with the detector (see column 5, lines 27+).

Akers et al. disclose an exemplary embodiment in Fig. 1 wherein the specimen is an aluminum alloy that is activated by a neutron source 12. Activation of copper atoms

in the specimen produces positron emitters, including ^{64}Cu and ^{62}Cu. They disclose that ^{62}Cu is produced from an (n,2n) reaction in ^{63}Cu. (The specification in Table I identifies ^{63}Cu and ^{62}Cu as among the plurality of precursors and positron emitters, respectively, that could be used to exercise the invention).

Richard B. Firestone, "The Berkeley Laboratory Isotopes Project, Exploring the Table of Isotopes," teaches that ^{62}Cu can be produced by any one of: a) charged particle reaction; b) photon reaction; or c) fast neutron activation (click on Cu on the Periodic Table of Elements to view Production Mode). Applicant's claim language, "photon source" reads on the expedient to generate the photons and effect the photon reaction taught by Firestone.

Therefore, it would have been obvious to one having ordinary skill of the art at the time the invention was made to modify the apparatus, as disclosed by Akers et al., by the teaching of Firestone, to substitute a photon source for a neutron source, to gain the advantages thereof (e.g., less unwanted activation products), as this is no more than the substitution of one technique for production of a positron emitter such as ^{62}Cu, by another well-known technique of producing the same radioisotope.

Note that it is immaterial how the ^{62}Cu is produced because it will emit positrons whether it is produced by either neutron or photon activation.

Obermayer teaches that one disadvantage of neutron activation in the non-destructive testing of materials is that the material or its container remains radioactive for a long period of time (see column 1, lines 55+). (This disadvantage is similar to the above-cited "unwanted activation products"). They teach the use of X-rays or gamma

rays, i.e., photon sources instead of neutrons. Thus, alternatively, it would have been obvious to one having ordinary skill of the art at the time the invention was made to modify the apparatus, as disclosed by Akers et al., by the teaching of Firestone and Obermayer, to substitute a photon source for a neutron source, to gain the advantages thereof (e.g., shorter radioactivity of material or its container), to substitute a photon source for a neutron source, as this is no more than the substitution of one technique for production of a positron emitter such as ^{62}Cu, by another well-known technique of producing the same radioisotope.

Applicant alleges in his Response to Final Action, the examiner's conclusion of obviousness is based upon improper hindsight reasoning, i.e., based on the teaching of the claimed invention. The Examiner disagrees because Akers clearly teaches the use of ^{63}Cu as a precursor, and the disadvantage of neutron irradiation compared to photon irradiation is a fundamental nuclear engineering principle that is well known to a nuclear artisan. The obviousness conclusion took into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and did not include knowledge gleaned only from the applicant's disclosure. Such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In any case, the additional cited prior art, i.e., Obermayer, provides further support that the use of photon irradiation is more advantageous than neutron irradiation, as previously stated by the Examiner.

6. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of the Akers et al.- Firestone combination or the Akers et al.-Firestone-Obermayer combination, as applied to claims 1, 5 and 8 above, and further in view of Miller (U.S. 4,980,901). Either one of the Akers et al.- Firestone combination or the Akers et al.-Firestone- Obermayer combination disclose the applicant's claims except for the use of an accelerator to generate photons.

Miller teaches the use of an electron accelerator to produce energetic bremsstrahlung x-rays that are sufficient for non-destructive examination of materials (see column 1, lines 39+). One having ordinary skill in the art would have recognized that the combinations and Miller are in the same field of endeavor, i.e., non-destructive testing. Therefore, it would have been obvious to one having ordinary skill of the art at the time the invention was made to modify the invention, as disclosed by either one of the Akers et al.- Firestone combination or the Akers et al.-Firestone- Obermayer combination, by the teaching of Miller, to have an accelerator for photon generation, gain the advantages thereof (e.g., capability to produce energetic photons), as this is no more than the use of a well known photon source in the art.

7. Claims 20-24 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of either Akers et al.-Firestone or Akers et al.-Firestone-Obermayer, in view of either one of Gedcke (ORTEC AN 59, "How Counting Statistics Controls Detection Limits and Peak Precision") or Simon Fraser University, Radiation Safety Office (Radiation Counting Statistics) and as a matter of optimization.

As to the Doppler broadening algorithm in claims 20 and 31, Akers et al. meets this limitation in view of Applicant's statement in the specification that his Doppler broadening algorithm 62 may comprise Akers et al.'s algorithm (see page 28, paragraph 0056 of the specification).

As to the selection of a normal activation/analysis process when the half-life of the positron emitter is greater than a predetermined half-life and the selection of a rapid activation/analysis process when said half-life is less than a predetermined value, this is a matter of optimization based on well-known principles. The difference between the two processes lies in the time duration of counting the emitted radiation from the sample. It is a notorious scientific principle that the accuracy and precision of the results of an activation analysis depends on the half-life of radioisotope whose radiation is being counted or measured. A short-lived radioisotope decays very rapidly and it may not register a statistically significant number of measured counts if the counting time is insufficient. Either one of Gedcke or Simon Fraser University teaches that counting time of a radioactive sample must be properly selected to ensure adequate accuracy and precision of the results. (Accuracy is a measure of the proximity of the measured value to the true value. Precision is indicative of the repeatability of the measured values). Note that these two references teach increasing the counting time when the number of counts is low, a condition that occurs when counting short-lived radioisotopes. See page 2 in Gedcke and page 3 in Simon Fraser University.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus, as disclosed by either one of

the Akers et al.- Firestone combination or the Akers et al.-Firestone- Obermayer combination, by the teaching of either one of Gedcke or Simon Fraser University, to use a normal activation/analysis process when the half-life of the positron emitter is greater than a predetermined half-life and to use a rapid activation/analysis process when said half-life is less than a predetermined value, because such modification is no more than the use of notorious scientific principles in the optimization of the process.

8. Claims 26, 27, 28 and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of either Akers et al. and Firestone alone or Akers et al. with Firestone and Obermayer, in view of IDS paper, "Positron Annihilation Spectroscopy."

The cited combinations disclose the Applicant's claims except for the use of two detectors, and Doppler broadening algorithm, positron lifetime algorithm and three-dimensional imaging algorithm, either alone or in combination of algorithms.

In Paper No. 14, Applicant states that said IDS paper "discusses the Doppler broadening, positron lifetime and 3-D imaging techniques, as well as methods for performing these techniques" (seepage 20, lines 1+). This paper teaches that positron defect spectroscopy is a selective and sensitive method of analyzing lattice defects and the use of these techniques, e.g., positron lifetime, provides a reliable and statistically very accurate parameter (see page 619, column 1). This paper also teaches the use of two detectors for higher precision in the measurements (see Fig. 3 and page 618, lines 3+).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus, as disclosed by either one of the Akers et al.- Firestone combination or the Akers et al.-Firestone- Obermayer combination, by the teaching of either one of IDS paper, "Positron Annihilation Spectroscopy", to use two detectors and Doppler broadening algorithm, positron lifetime algorithm and three-dimensional imaging algorithm, either alone or in combination, to gain the advantage thereof (e.g., high accuracy and precision) because such modification is no more than the use of a well-known detector configuration and algorithms in the art.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rick Palabrica whose telephone number is 703-306-5756. The examiner can normally be reached on 7:00-4:30, Mon-Fri; 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Carone can be reached on 703-306-4198. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RJP
September 22, 2004

MICHAEL J. CARONE
SUPERVISORY PATENT EXAMINER